Remarks

Upon entry of the forgoing amendments claims 24-51 are pending in the application. Claim 1-23 have been cancelled without prejudice or disclaimer. Claim 25 has been amended to correct a typographical error contained therein. The amendment does not introduce any new subject matter within the meaning of 35 U.S.C. §132. Therefore, entry of the amendments is respectfully requested.

SUMMARY OF RESTRICTION REQUIREMENT

The Examiner has required restriction of claims 24-51 under 35 U.S.C. §§ 121 and 372, as follows:

Group I: claims 24, and 25-41, drawn to a method for prevention or treatment of prostatic cacinomas and the pharmaceutical composition which influences the expression or function of proteins synthesized or secreted by tumors;

Group II: claims 25, and 45-51, drawn to a method for diagnosing unspecified disorders associated with tumors; and

Group III: claims 42 and 43, drawn to a kit comprising at least one substance for detecting expression or function proteins synthesized or secreted by unspecified tumors.

Additionally, the Examiner has required restriction of species from each of the following three groupings as follows:

From the species of substance or active ingredient as recited in claims 28-31, 35-37, 39-41, and 47-49:
(a) a polynucleotide,
(b) a peptide, or
(c) a small molecule compound.

From the mode of administration of active ingredient as claimed in claims 33 and 51:

(d) oral,
(e) intravenous,
(f) topical, or
(g) inhalation.

From the target of the active ingredient as recited in claims 28 and 38-40:

(h) activators,
(i) inhibitors,
(j) regulators, or
(k) biological precursors.

PROVISIONAL ELECTION

Applicants provisionally elect the invention of Group II above, and the species (b) polypeptide, (e) intravenous, and (i) inhibitors, with traverse.

TRAVERSAL

Applicants respectfully traverse the Examiner's restriction requirement.

The restriction requirement is traversed because the Examiner has used as basis for the requirement, lack of unity under PCT Rule 13.1. Applicants respectfully submit that the claims of Group II and the claims of Group III possess "unity of invention" because they share a special technical feature as required by PCT Rule 13.2.

PCT Rule 13.2 states the following, in relevant part:

> "[T]he requirement of unity of invention referred to in Rule 13.1 shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression 'special technical features' shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art."

In the present application, the special technical feature that is shared between Group II, the "diagnostic reagent" claims, and Group III, the "diagnostic kit" claims, is the "diagnostic reagent" itself.

Furthermore, the restriction between alleged species (a)-(c) above is not essential. It is known to those of ordinary skill in the art that specific molecules, differentiated by alleged species (a)-(c), can be generated, designated, selected, or otherwise obtained to bind with high affinity and specificity to any diagnostic target. Therefore, it would follow that having discovered the diagnostic value of any particular protein, all methods of detection of that protein would be known to the person who discovered the diagnostic value. Therefore, the present claims are justified in claiming all of the subject matter of (a)-(c). With the provisional election of Group II, drawn to diagnostics, the subject matter of (a)-(c) should not be separated for the purposes of diagnostic application.

Moreover, the restriction between alleged species (d)-(g) above is also not essential. As there are a number of possible routes of administration for the reagent of the present invention, restriction to a single one is unnecessary and is contrary to the principles of patent law in general. The complications and legal grey zones created by such a restriction make it improper.

Regarding species (h)-(k), each of these alleged species share similar functions. Therefore, concurrent examination of (h)-(k) does not cause any serious burden on the Examiner. *See* MPEP § 803, infra.

Furthermore, any restriction of the claims based on the groups and species suggested by the Examiner would place an undue burden upon the Applicants with regard to commercialization of the invention. As all of the groups and species are closely related, any intellectual property right stemming from this application should issue concurrently.

Additionally, the requirement omits "an appropriate explanation" as to the existence of a "serious burden" if a restriction were not required. *See* MPEP § 803. Regardless of any differences which may exist between the inventions set forth in the different groups, a complete and thorough search for the invention set forth in any one of the groups would require searching the art areas appropriate to the other groups. Since a search of each of the inventions of the groups would be coextensive, it would not be a serious burden upon the Examiner to examine all of the claims in

this application.

Further, at the Examiner's disposal are powerful electronic search engines providing the Examiner with the ability to quickly and easily search all of the claims. Considering that the Examiner will most likely undertake a search for the power plant of claim 34, searching for the power plant of other independent claims would be minimally burdensome on the Examiner.

Moreover, given the overlapping subject matter and identical classifications of the species, examinations of all the invention groups would not pose a serious burden because they would be coextensive. Further, the fact that various claims may fall under different U.S. Patent and Trademark Office classes does not necessarily make them independent or distinct inventions. The classification system at the U.S. Patent and Trademark Office is based in part upon administrative concerns and is not necessarily indicative of separate inventive subject matter in all cases.

Furthermore, applicants have paid a filing fee for an examination of all the claims in this application. If the Examiner refuses to examine the claims paid for when filing this application and persists in requiring applicants to file divisional applications for each of the groups of claims, the Examiner would essentially be forcing applicants to pay duplicative fees for the non-elected or withdrawn claims, inasmuch as the original filing fees for the claims (which would be later prosecuted in divisional

applications) are not refundable.

Finally, Applicants note that upon allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. 1.141.

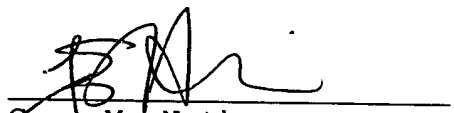
CONCLUSION

In view of the foregoing, Applicants respectfully request the Examiner to reconsider and withdraw the requirement for claim restriction and election of species and examine all claims pending in this application.

If the Examiner has any questions or wishes to discuss this application, kindly telephone the undersigned at the below-listed number.

Respectfully submitted,

NATH & ASSOCIATES PLLC



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